REMARKS/ARGUMENTS

Claims 1-15, 17-53, 55-61 and 63 are pending in this application. Nos. 1-15, 17-41, 43-53, 55-59, 61 and 63 are rejected while nos. 42 and 60 are objected to.

In this response claims 1, 41, 42, 59 and 60 are amended. The amendments to claims 1, 41 and 59 are of a typographical nature and are not believed to affect the claim scope. Claims 42 and 60 are re-written in independent form including the limitations of the base claim and any intervening claims. The claim revisions are all entirely supported by the application as originally filed and thus they raise no issue of new matter. Entry of the amendments is, therefore, respectfully requested. Upon such entry claims 1-15, 17-53, 55-61 and 63 as amended will be pending in the application.

Reconsideration of the application is respectfully requested in light of the claim amendments and remarks presented herein.

Allowable Subject Matter

Applicants note with appreciation the Examiner's indication in ¶16 on p. 17 of the Office Action that claims 42 and 60 contain allowable subject matter. The claims have thus been re-written in independent form in a manner which is believed to overcome the claim objections set forth in the Office Action. Claims 42 and 60 as amended are, therefore, believed to be in condition for allowance.

Objections to the Claims

In ¶3 on p. 3 of the Office Action claims 1, 41, 42, 59 and 60 are objected to. These claims have, therefore, been amended in a manner which is believed to overcome the objections, i.e., a comma has been inserted in claim 1 at line 4 and in claims 41, 42, 59 and 60 applicants have changed "NH2" to "NH_2".

The Examiner is respectfully requested to reconsider and withdraw the various claim objections.

Rejections Under 35 U.S.C. §112, Second Paragraph

In ¶2 on pp. 2-3 claims 1-15, 17-36, 43-48, 50-53, 61 and 63 are rejected under 35 U.S.C. §112, second paragraph. The Examiner states that the subject claims fail to correspond in scope with that which applicants regard as their invention.

As evidence in support of the above-described rejection the Examiner cites to ¶6 of the Declaration Under 37 C.F.R. §1.132 by Inventor Stern filed July 28, 2009 and p. 16 lines 1-4 in the Remarks filed July 28, 2009. The Examiner points out that in the Declaration and in the accompanying Remarks applicants have stated that naturally occurring LHRH is not amidated at its C-terminus and that LHRH which is amidated at its C-terminus is amidated at a location where the peptide is not naturally amidated. The Examiner then cites several publications which demonstrate that the indicated statements are not technically correct.

In response, applicants concede that naturally occurring LHRH is in fact amidated at its C-terminus and thus the statements pointed out by the Examiner require an explanation. The statements were made due to a misunderstanding between applicants and their counsel with regard to Example 4 at pp. 57-59 discussing the effect of C-terminal amide on the intraduodenal absorption of LHRH in rats. The Experiment was carried out by Inventor Stern to demonstrate that amidated LHRH has greater bioavailability than non-amidated LHRH and not to show an improvement attributable to amidating a peptide at a location that is not naturally amidated.

It has now been further explained to applicants' counsel that in carrying out the experiments, the inventor obtained commercially available non-amidated LHRH (wherein the C-terminal amino acid is gly-COOH instead of gly-NH_2) and then compared the effect of this material with that of natural LHRH which is amidated at the C-terminus. Thus, since the original LHRH material was not amidated, the latter material (i.e., amidated at the C-terminus) was characterized in the discussion between the inventor and counsel as being a peptide that was amidated at a location "not naturally amidated".

Due to the misunderstanding, therefore, the statement was made that LHRH is <u>not</u> naturally amidated and had, in fact been amidated (i.e., at a location not naturally amidated) [in Example 4] for purposes of exemplifying the subject matter of the invention, i.e, that active peptide agents amidated at a location that is not naturally amidated display improved bioavailability when orally administered to a subject. This characterization of natural LHRH as

being not naturally amidated is, however not correct and applicants regret any confusion caused due to the above-described misunderstanding.

Furthermore, an Information Disclosure Statement is also being filed concurrently with this Amendment to ensure that the record is entirely clear with regard to the facts as set forth above. Applicants further submit, therefore, that the results of Example 4 which demonstrate that amidated LHRH has greater bioavailability than non-amidated LHRH are thus not commensurate with the claims pending in the present application (see also the Examiner's discussion in regard to this issue at p. 16, second paragraph, of the Office Action).

In light of the explanation provided above the Examiner is respectfully requested to reconsider and withdraw the rejection of applicants' claims under 35 U.S.C. §112, second paragraph.

Rejections Based on the Prior Art

In ¶6 on pp. 3-4 of the Office Action, claims 1-8, 12-15, 17-36, 43-47, 49-51, 61 and 63 are rejected under 35 U.S.C. §102(b) over Stern et al. USP 6,086,918 as evidenced by the Schally lecture (Nobel lecture, 08 December 1977), Constantinides et al. (U.S. Patent Application Publication No. 2005/0079145) and Shields USP 3,853,834. The Office Action states that the Stern '918 reference teaches oral administration of luteinizing hormone-releasing factor (a synonym for "LHRH") using a carrier comprising a pH-lowering agent, an absorption enhancer, a non-physiologically active protein, a gelatin capsule and an enteric coating. The Schally, Constantinides and Shields references are cited, according to the Action, for their teaching that LHRH is amidated at its C-terminus. The rejection is respectfully traversed.

In the discussion above regarding the rejection under 35 U.S.C. 112, second paragraph, applicants conceded that their previous response indicating that LHRH amidated at the C-terminus is an example of a peptide amidated at a location that is not naturally amidated was incorrect. That is, as acknowledged above natural LHRH is, in fact, amidated at its C-terminus. Applicants broadest independent composition claim (no. 1) and independent method claim (no. 45), however, are directed to active peptide agents that are amidated at a location that is **not** naturally amidated. Neither Stern '918 nor any of the Schally, Constantinides and/or Shields references disclose or even suggest an oral pharmaceutical composition comprising a peptide that

is amidated at a location that is not naturally amidated, or a method for enhancing the bioavailability of an orally delivered physiologically active peptide agent wherein the agent is a peptide that is amidated at a location that is not naturally amidated.

Since, therefore, the Stern reference does not disclose each and every feature of applicants' claimed composition and method when taken by itself, nor even when combined with any or all of the Schally, Constantinides et al. and/or Shields reference, the rejected claims are believed to distinguish over the cited art, i.e., they are not anticipated. Thus, it is respectfully requested that the §102(b) rejection of applicants' claims 1-8, 12-15, 17-36, 43-47, 49-51, 61 and 63 be withdrawn.

In ¶7 on pp. 4-5 claims 5 and 48 are rejected under 35 U.S.C. §103 over Stern et al. '918 as evidenced by Schally, Constantinides et al. and Shields and further in view of Stern et al. USP 5,912,014. According to p. 5 of the Action Stern '014 is cited due to its disclosure of salmon calcitonin made with a C-terminal glycine extension which is enzymatically converted to an amide group. The rejection is respectfully traversed.

Claim 5 is ultimately dependent from independent composition claim 1 while claim 48 is ultimately dependent upon independent method claim 45. The dependent claims each include all of the features contained in the independent claim from which they depend, including the use of a active peptide component that is amidated at a location that is not naturally amidated. As noted above, neither Stern '918 nor any of the Schally, Constantinides et al. and/or Shields references disclose, or even suggest this feature. Nor is it taught or suggested by the reference newly added to the combination, i.e., Stern '014. Thus since none of the references combined to reject claims 5 and 48 contain any teaching or suggestion of making the composition, or practicing the method, as claimed, i.e., wherein the active peptide agent is amidated at a location that is not naturally amidated, applicants respectfully submit that the rejected claims 5 and 48 are not in fact obvious over any or all of the references combined to reject the claims.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the subject rejection.

In ¶8 on pp. 5-6 claims 1-15, 17-36, 43-47, 49-53, 61 and 63 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by WO 02/043767 of Unigene Laboratories, Inc. (Stern et al.) as evidenced by Schally, Constantinides et al. and Shields. The rejection is similar to that set forth

in ¶6 of the Office Action (discussed above) except that a different 'primary' reference is relied upon instead of the Stern et al U.S. Patent 6,086,918, namely an International application of Stern et al. that teaches, according to p. 5 of the Office Action, oral administration of luteinizing hormone-releasing factor (LHRH) linked to a membrane translocator using a carrier comprising a pH-lowering agent, a protease inhibitor, an absorption enhancer, a non-physiologically active peptide, a gelatin capsule and an enteric coating. The remaining references are, once again, cited due to their teaching that LHRH is amidated at its C-terminus. This rejection is also respectfully traversed, i.e., on essentially the same basis as the rejection in ¶6 of the Action.

Accordingly, in the discussion above regarding the rejection under 35 U.S.C. 112, second paragraph, applicants conceded that their previous response indicating that LHRH amidated at the C-terminus is an example of a peptide amidated at a location that is not naturally amidated was incorrect. That is, as acknowledged above natural LHRH is, in fact, amidated at its C-terminus. Applicants broadest independent composition claim (no. 1) and independent method claim (no. 45), however, are directed to active peptide agents that are amidated at a location that is **not** naturally amidated. Neither WO 02/043767 nor any of the Schally, Constantinides and/or Shields references disclose or even suggest an oral pharmaceutical composition comprising a peptide that is amidated at a location that is not naturally amidated, or a method for enhancing the bioavailability of an orally delivered physiologically active peptide agent wherein the agent is a peptide that is amidated at a location that is not naturally amidated.

Since, therefore, the International publication does not disclose each and every feature of applicants' claimed composition and method when taken by itself, nor even when combined with any or all of the Schally, Constantinides et al. and/or Shields reference, the rejected claims are believed to distinguish over the cited art. Thus, the anticipation rejection under 35 U.S.C. §102(a) of applicants' claims 1-8, 12-15, 17-36, 43-47, 49-51, 61 and 63 should be withdrawn by the Examiner.

The next rejection, i.e., that of claims 5 and 48 in ¶9 on pp. 6-7 under 35 U.S.C. §103 over WO 02/043767 as evidenced by Schally, Constantinides et al. and Shields, and further in view of Stern et al. USP 5,912,014, is similar in nature to the rejection contained in ¶7 of the Action on pp. 4-5 (see the discussion above). The difference is in the identity of the 'primary' reference, which is WO 02/043767 instead of Stern et al USP6,086,918. Nevertheless,

applicants' argument against the subject rejection is essentially the same as that which was raised to the rejection contained in ¶6 of the Action.

That is, claim 5 is ultimately dependent from independent composition claim 1and claim 48 is ultimately dependent upon independent method claim 45. The dependent claims both include all of the features contained in the independent claim from which they depend, including the use of a active peptide component that is amidated at a location not naturally amidated. As noted above, neither WO 02/043767 nor any of the Schally, Constantinides et al. and/or Shields references disclose, or even suggest this feature. Nor is it taught or suggested by the reference newly added to the combination, i.e., Stern '014. Thus since none of the references combined to reject claims 5 and 48 contain any teaching or suggestion of making the composition as claimed, or practicing the method as claimed, i.e., wherein the active peptide agent is amidated at a location that is not naturally amidated, applicants respectfully submit that the rejected claims 5 and 48 are not in fact obvious over any or all of the references combined to reject the claims.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the 'obviousness' rejection of the claims under §103.

In ¶10 on pp. 7-9 claims 1-8, 12-15, 17-41, 43-47, 49-51, 55-59 and 63 are rejected under 35 U.S.C. §103 over Stern et al. USP 6,086,918 in view of Habener (USP 5,120,712) or Balschmidt et al. (USP 5,157,021), or Barbier et al. (USP 6,110,892), or European Patent No. 0 878 201 (Tamura et al.), or Neiss et al. (USP 4,804,742). Stern et al. is cited due to its disclosure relating to the oral administration of peptides such as insulin, salmon calcitonin, parathyroid hormone and lhrf using a carrier comprising a pH-lowering agent, an absorption enhancer, a non-physiologically active protein, a gelatin capsule and an enteric coating. The reference states further that Stern et al do not teach peptides which are amidated GLP-1 analogs, amidated insulin analogs or amidated PTH analogs. The Examiner thus combines the primary Stern et al. '918 reference with various 'secondary' references that do disclose amidated peptides wherein the amidation is at a location that is not naturally amidated. The rejection is respectfully traversed.

Notwithstanding the teachings contained in the various secondary references with regard to amidated peptides amidated at a location that is not naturally amidated, applicants respectfully submit that the rejected claims would not be obvious to one having an ordinary level of skill in

this art over the combination of the primary Stern et al. reference and one or more of the secondary references. This is due to the fact that none of the secondary references, or the primary reference for that matter, contain a teaching or disclosure that the amidation of a peptide active agent and its inclusion in an orally administered formulation would serve to impart any improved bioavailability of the peptide - as is specifically recited in both independent composition claim 1 and independent method claim 45.

Applicants submit that this lack of a teaching in the references combined to reject the claims, i.e., that oral administration of the peptide active agent at a location that is not naturally amidated serves to enhance the bioavailability of the peptide, as demonstrated in the Stern July 28, 2009 declaration under 37 C.F.R. 1.132 (i.e., excepting the portion regarding amidated LHRH which, as stated above, was not correct and is thus withdrawn) leads to the conclusion that there is no basis to support the combination of one or more of the secondary references with the primary reference. That is, applicants' invention is based, at least in part, on the discovery that administering an oral pharmaceutical formulation including, as a component, an active peptide agent that is amidated at a location that is not naturally amidated, leads to an unexpected enhancement in the bioavailability of the peptide agent. Since neither the primary nor the secondary references evince any recognition of this feature, applicants submit that there is no basis which would suggest to a skilled artisan that the references should be combined. Due to the lack of any teaching suggesting the proposed combination, therefore, applicants respectfully submit that the subject claims would not be obvious to the one of ordinary skill.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection of claims 1-8, 12-15, 17-41, 43-47, 49-51, 55-59 and 63 under 35 U.S.C. §103.

In ¶11 on p. 9 of the Action claims 5 and 48 are rejected under 35 U.S.C. §103 over Stern et al. '918 in view of Habener, or Barbier et al., EP '201 (Tamura et al.), or Neiss et al. as applied in the rejection discussed above, and further in view of Stern et al. USP 5,912,014. Stern '014 is cited due to its teaching of salmon calcitonin made with a C-terminal glycine extension which is enzymatically converted to an amide group. The rejection is respectfully traversed for the reasons set forth below.

Claims 5 and 48 are dependent claims which depend, respectively, on independent composition claim 1 and independent method claim 45. As such, the rejected dependent claims

include all of the features contained in the independent claims from which they depend, i.e., including that of a physiologically active peptide agent amidated at a location that is not naturally amidated. As noted above, notwithstanding the teachings contained in any (or all) of the secondary Habener, Barbier et al., EP '201 and/or Neiss et al references with regard to peptide agents that are amidated at a location that is not naturally amidated, there is no teaching or suggestion to be found within the secondary references that the inclusion in an oral pharmaceutical composition of a physiologically active peptide agent that is amidated at a location not normally amidated would have an unexpectedly beneficial effect on the bioavailability of the subject peptide. This improvement is evidenced in the Stern declaration of July 28, 2009 (notwithstanding the statements and conclusions described above regarding the amidation of LHRH). In sum, neither Stern '918, nor any of the secondary references listed above suggest an improvement in bioavailability of the peptide active agent attributable to the inclusion of a peptide amidated at a location not naturally amidated, and thus there would be no impetus to modify the composition disclosed in Stern '918 to include one or more of the amidated peptides cited in any of the secondary references.

Nor is any such teaching contained in the additional Stern '014 secondary reference which forms a part of the combination cited by the Examiner in support of the subject rejection. The reference is included, as indicated above, due to its teachings regarding the formation of glycine-extended precursors and then converting the glycine residue to a C-terminal amide group. The reference, however, contains no teaching or even a suggestion that an active peptide agent amidated at a location where the peptide is not naturally amidated would provide an improved level of bioavailability in an orally administered. Thus, even the addition of Stern '014 to the combination of references discussed previously would not, in applicants' view, lead one having an ordinary level of skill in the relevant art toward either the claimed oral pharmaceutical composition or the claimed method, i.e., as recited in, e.g., claims 1 and 45.

For the reasons presented above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 5 and 48 under 35 U.S.C. §103.

In ¶12 on pp. 9-11 claims 1-15, 17-41, 43-47, 49-53, 55-59 and 63 are rejected under 35 U.S.C. §103(a) over International application No. 02/043767 of Unigene Laboratories, Inc. (Stern et al.) in view of Habener, or Balschmidt et al., or Barbier et al., or EP 0 878 201 or Neiss. This

rejection is similar in nature to that set forth in ¶10 on pp. 7-9 as discussed above, except that a different 'primary' reference is relied upon instead of the Stern et al U.S. Patent 6,086,918, namely an International application of Stern et al. that teaches, according to p. 10 of the Office Action, oral administration of luteinizing hormone-releasing factor (LHRH) linked to a membrane translocator using a carrier comprising a pH-lowering agent, a protease inhibitor, an absorption enhancer, a non-physiologically active peptide, a gelatin capsule and an enteric coating. The remaining references are, once again, cited due to their teaching of amidated peptides that are amidated at a location that is not naturally amidated. This rejection is also respectfully traversed, i.e., on essentially the same basis as the rejection in ¶10 of the Action.

Notwithstanding the teachings contained in the various secondary references with regard to amidated peptides amidated at a location that is not naturally amidated, applicants respectfully submit that the subject claims would not be obvious to one having an ordinary level of skill in this art over the combination of the primary Stern et al. International publication and one or more of the secondary references. This is due to the fact that none of the secondary references, or the primary reference for that matter, contain any teaching or disclosure that the amidation of a peptide active agent and its inclusion in an orally administered formulation would serve to impart any improved bioavailability of the peptide as is specifically recited in both independent composition claim 1 and independent method claim 45.

Applicants submit that this lack of a teaching in any of the references combined in support of the rejection that oral administration of the peptide active agent at a location that is not naturally amidated serves to enhance the bioavailability of the peptide, i.e., as demonstrated in the Stern July 28, 2009 declaration under 37 C.F.R. 1.132 (i.e., excepting the portion regarding amidated LHRH which, as stated above, was not correct and is thus withdrawn) leads to the conclusion that there is no basis to support the combination of one or more of the secondary references with the primary reference. That is, applicants' invention is based, at least in part, on the surprising discovery that administering an oral pharmaceutical formulation including, as a component, an active peptide agent that is amidated at a location that is not naturally amidated, leads to an unexpected enhancement in the bioavailability of the peptide agent. Since neither the primary nor the secondary references evince any recognition of this feature, applicants submit that there is no basis for suggesting to a skilled artisan that the references should be combined.

Due to the lack of any teaching suggesting the proposed combination, therefore, applicants respectfully submit that the subject claims would not be obvious to the one of ordinary skill.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection of claims 1-15, 17-41, 43-47, 49-53, 55-59 and 63 under 35 U.S.C. §103.

In ¶13 on p. 11 of the Action, claims 5 and 48 are rejected under 35 U.S.C. §103 over Stern et al. '918 in view of Habener, or Barbier et al., EP '201 (Tamura et al.), or Neiss et al. as applied in the rejection discussed above, and further in view of Stern et al. USP 5,912,014. Stern '014 is cited due to its teaching of salmon calcitonin made with a C-terminal glycine extension which is enzymatically converted to an amide group. The rejection is respectfully traversed for the reasons set forth below.

Claims 5 and 48 are dependent claims which depend, respectively, on independent composition claim 1 and independent method claim 45. As such, the rejected dependent claims include all of the features contained in the independent claims from which they depend, i.e., including that of a physiologically active peptide agent amidated at a location that is not naturally amidated. As noted above, notwithstanding the teachings contained in any (or all) of the secondary Habener, Barbier et al., EP '201 and/or Neiss et al references with regard to peptide agents that are amidated at a location that is not naturally amidated, there is no teaching or suggestion within the secondary references to the effect that the inclusion in an oral pharmaceutical composition of a physiologically active peptide agent that is amidated at a location not normally amidated would have an unexpectedly beneficial effect on the bioavailability of the subject peptide. This improvement is evidenced in the Stern declaration of July 28, 2009 (notwithstanding the erroneous statements noted above regarding LHRH). In sum, neither WO 02/043767, nor any of the secondary references listed above suggest an improvement in bioavailability of the peptide active agent attributable to the inclusion of a peptide amidated at a location not naturally amidated, and thus there would be no impetus to modify the composition disclosed in the International publication to include one or more of the amidated peptides cited in any of the listed secondary references.

Nor is any such teaching contained in the additional Stern '014 secondary reference added to the combination in the subject rejection. The reference is included, as indicated above, due to its teachings in regard to the formation of glycine-extended precursors and then converting the

glycine residue to a C-terminal amide group. The reference, however, contains no teaching or even a suggestion that an active peptide agent amidated at a location where the peptide is not naturally amidated would provide an improved level of bioavailability when orally administered. Thus, even the addition of Stern '014 to the combination of references discussed previously would not, in applicants' view, lead one having an ordinary level of skill in the relevant art toward either the claimed oral pharmaceutical composition or the claimed method, i.e., as recited in, e.g., claims 1 and 45.

For the reasons presented above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 5 and 48 under 35 U.S.C. §103 as described in ¶13 of the Office Action.

In ¶14 on pp. 12-13 claims 1, 4, 5, 17-19 and 41 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by the Neugebauer et al. article (Biochemistry, Vol. 34, pp. 8835-8842). The rejection is respectfully traversed.

In citing the Neugebauer article against applicants' claims the Examiner alleges (Office Action p. 12) that, "inherently the composition of the Neugebauer article will provide enhanced bioavailability of the amidated peptide [i.e., hPTH(1-31)NH_2] when it is orally delivered to the same extent claimed by Applicants.". Applicants respectfully disagree, however, with this unsupported conclusion. The article contains no teaching that the amidation of the peptide, i.e., at a location that is not naturally amidated, will improve its bioavailability. What the reference actually teaches is that the amidation will increase the alpha helix in the molecule and therefore increase receptor binding. As would be well known to those having at least an ordinary level of skill in the relevant art, it is entirely possible for a peptide to bind well to its receptor while, yet, having very poor bioavailability when the peptide is delivered orally. There is no teaching or disclosure within the reference to establish that there is any positive correlation between increased receptor binding and an improvement in bioavailability upon oral delivery.

Based on the reasons provided above, therefore, the Examiner is respectfully requested to reconsider and withdraw the anticipation rejection under 35 U.S.C. §102(b) of applicants' claims 1, 4, 5, 17-19 and 41 over the Neugebauer et al. article.

In paragraph 15 of the Action the Examiner sets forth his responses to the arguments previously submitted by applicants in their prior response filed July 28, 2009.

In response to the Examiner's comments on pp. 13-14 of the Action, applicants acknowledge that there was confusion in their interpretation regarding LHRH in the previous response - see the discussion above regarding the rejection under 35 U.S.C. §112, second paragraph and in the accompanying Information Disclosure Statement filed herewith. To clarify the record applicants are stating herein that LHRH amidated at its C-terminus falls outside the scope of the present claims. Nevertheless, an oral pharmaceutical composition along the lines recited in, e.g., claim 1 - wherein the active peptide agent is LHRH amidated at a location where it is not naturally amidated does fall within the scope of applicants' claims. In fact, the present application includes a claim (no. 61) drawn to just such a composition. Based on the explanations provided in the present response, claim 61 would not, however, encompass LHRH amidated at its C-terminus. To that end, therefore, Example 4 provided in the present application and discussed in the Stern July 28, 2009 declaration, is not representative of the presently claimed composition. Applicants regret and again apologize for the confusion caused due to the statements regarding LHRH in their prior response.

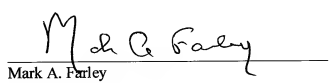
Furthermore, on p. 15 the Examiner mentions the Liebisch et al. article discussed in Dr. Stern's declaration. Notwithstanding the showing contained in the article that the amidation of a peptide at the C-terminus confers carboxypeptidase Y resistance, applicants submit that there is no correlation demonstrated by the subject reference between CPY resistance and increased bioavailability in oral delivery.

Summary

For the reasons presented above the Examiner is respectfully requested to reconsider and withdraw the various objections and rejections of applicants' claims and to issue a Notice of Allowance with respect to the claims in the form now pending.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON March 18, 2010.

Respectfully submitted,



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